4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3404]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Drug User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0727. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Drug User Fee Program

OMB Control Number 0910-0727—Revision

This information collection supports implementation of FDA's Generic Drug User Fee program. The Generic Drug User Fee Amendments (GDUFA) (Pub. L. 112-144, Title 111) were enacted to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA authorizes FDA to assess user fees to fund critical and measurable enhancements to the performance of FDA's generic drugs program, bringing greater predictability and timeliness to the review of generic drug applications. GDUFA is currently authorized through September 30, 2022, with reauthorization activities currently underway. For more information regarding GDUFA and ongoing implementation, we invite you to visit our website at https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments.

GDUFA is based on an agreement negotiated by FDA and representatives of the generic drug industry intended to address continuing regulatory challenges. GDUFA reflects input received during an open process that includes regular public meetings, posting of meeting minutes, and consideration of comments from a public docket. We are revising the information collection to include the current GDUFA agreement, or "goals letter," as reflected in the document "GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022," available for download from our website at https://www.fda.gov/media/101052/download. The performance goals and program enhancements specified in the goals letter apply to aspects of the generic drug review program that are important for facilitating timely access to quality, affordable generic medicines. FDA is committed to meeting the performance goals specified in the goals letter and to continuous improvement of its performance.

Included among the performance goals is the issuance of topic-specific guidance documents. We maintain a searchable guidance database on our website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents. In publishing the

respective notices of availability for each guidance document, we include an analysis under the PRA and invite public comment on the associated information collection recommendations. In addition, all Agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We have developed Form FDA 3794, the Generic Drug User Fee Cover Sheet, available at https://www.fda.gov/industry/fda-user-fee-programs which requests the minimum necessary information from generic drug applicants to account for and track user fees and to determine the amount of the fee required. Applicants complete and submit the cover sheets to accompany payments. While applicants may submit payment through multiple means, all cover sheets are prepared using FDA's web-based electronic User Fee System. Upon submitting the completed cover sheet, the User Fee System generates a user fee identification number, which is provided to applicants at the bottom of the cover sheet. It also notes the correct fiscal year user fee assessment that is due for the submission or program. FDA requests that applicants submit a copy of this completed cover sheet along with the abbreviated new drug application, as well as other additional GDUFA fees, so FDA can verify that the applicant has paid the correct user fee and their account is current.

Respondents to the information collection are potential or actual generic drug application holders or related active pharmaceutical ingredient and finished dosage form manufacturers. Companies with multiple user fee obligations may submit a cover sheet for each user fee obligation.

In the *Federal Register* of November 19, 2021 (86 FR 64945), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Form FDA 3794	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours

Generic Drug User Fee Cover Sheet	500	7.616	3,808	0.5 (30 minutes)	1,904

[1] There are no capital costs or operating and maintenance costs associated with this collection of information

Based on a review of the information collection, we have retained the currently approved burden estimate.

Dated: February 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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